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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,012	12/08/2005	Jean-Baptiste E. Blanc	PU4832USW	1078

23347 7590 04/07/2009

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EXAMINER	
BASQUILL, SEAN M	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
04/07/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/560,012	BLANC ET AL.	
	Examiner	Art Unit	
	Sean Basquill	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7,9,11,13,15-33,35 and 42-46* is/are pending in the application.

4a) Of the above claim(s) *42,45 and 46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7,9,11,13,15-33,35 and 42-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8 Dec 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Invention I, Claims 1-33, 35, 43, and 44 in the reply filed on 23 February 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). For purposes of clarification, the examiner regrets not specifically identifying in the previous action the exact compound relied upon to break unity. Para amino benzoic acid, listed on page 217 of the Sigma catalog, anticipates the genus as taught in instant Claim 1.

Applicant's cancellation of Claims 4, 6, 8, 10, 12, 14, 34, 36-41 and amendment of Claims 1, 9, 11, 13, 15-17, 19, 20, and 27 have been entered.

Applicants' election of 4-[(cyclopropylmethyl)(propyl)amino]-2-(trifluoromethyl)benzonitrile as the species of Formula I is hereby acknowledged, as is the applicant's indication of Claims 1-3, 5, 7, 9, 11, 13, 15, 17-20, 27-33, 35, 43, 44 as readable on the elected species of Formula I.

As will appear from the following, the examiner has found the species of compound elected by applicants, 4-[(Cyclopropylmethyl)(propyl)amino]-2-(trifluoromethyl)benzonitrile, to be free of the art. The examiner therefore has WITHDRAWN the species election, and examined the pending claims as though no election were made.

Claims 4, 6, 8, 10, 12, 14, 34, 36-41 having been cancelled, instant Claims 1-3, 5, 7, 9, 11, 13, 15-33, 35, 43, 44 are presented for examination.

Priority

2. Applicant's claims for the benefit of the prior-filed international and provisional applications PCT/US04/18252 and 60/477,252 under 35 U.S.C. 119(e) and under 35 U.S.C. 365(c) are acknowledged.

Claim Rejections - 35 USC § 112 First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-3, 5, 7, 9, 11, 13, 15-28, 30-32, 35, and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See*, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "solvates, and physiologically functional derivatives thereof" used herein), however, may not suffice to meet the written description requirement.

This is particularly true when a compound is claimed in purely functional terms. *See Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful solvates and physiologically functional derivatives thereof generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of compound species at pages 27-

31, none of which are salts, solvates, or physiologically functional derivatives thereof. In terms of solvates, applicants disclose only three (water, ethanol, and acetic acid solvates generally) on page 17. Likewise, applicants disclose only two generic categories of derivatives, esters and amides, also on page 17. These are not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

4. Claims 1-3, 5, 7, 9, 11, 13, 15-20, 27, 28, 30-32, 35, and 44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See*, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984) (holding that a claim was not adequately described because the specification did 'little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.')

Mere indistinct terms (such as "C1-6 aryl, 3-10 membered heterocyclyl, aryl, aralkyl, heteroaryl or heteroaralkyl" used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. *See Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

> The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Univ. of Calf. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997).

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful C1-6 alkyl, haloalkyl, alkoxy, haloalkoxy, aryl, C2-6 alkenyl, alkynyl, 3-10 membered heterocyclyl, aryl, aralkyl, heteroaryl or heteroaralkyl, hydroxyalkyl, cycloalkyl, formyl, and azido generally, a potentially huge genus inclusive of many different compounds having widely divergent structures and functions. Specifically, the specification discloses only a limited number of compound species at pages 27-31. These are not viewed as being reasonably

representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus.

Claim Rejections - 35 USC § 112 Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 9, 11, 13, 15, 27, and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims fail to indicate which substituents of those enumerated in Claim 1 (R_1-R_{12}) are to have the additional limitations imposed.

6. Claims 1-3, 16, 17, 27, 28, 30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, "n" as used in Claim 1 to define the substituent R_3 has not been defined.

7. Claim 5 recites the limitation "the compound of Claim 4." Because Claim 4 has been cancelled, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 30 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by the 1989 Sigma Chemical Company Catalog (of record).

The Sigma Chemical Company catalog from 1989 discloses p-amino benzoic acid. (Pg.217).

9. Claims 1-3, 17-20, and 29-32 rejected under 35 U.S.C. 102(b) as being anticipated by D.E. Grocock, *et al*, *Steric Effects in Di- and Tri-arylmethane Dyes*, J.C.S. PERKIN II, 1792 (1973) (hereinafter "Grocock"), as evidenced by Veronique Scailteur and Robert Lauwerys, *In Vivo Metabolism of Dimethylformamide and Relationship to Toxicity in the Male Rat*, 56 ARCH. TOXICOL. 87 (1984) (hereinafter "Scailteur").

Grocock describes 4-dimethylamino-2-trifluoromethylbenzonitrile in dimethylformamide. (Pg. 1795). Scailteur indicates that dimethylformamide is a solvent safe and useful for administration to animals. (Pg. 87).

10. Claims 1-3, 18, 30-33, 35, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by G. Mansour, *et al*, *Synthesis and Physical Characterization of Some New Hydrophobic Forms of the Solvatochromic N,N-dialkyl-p-nitroanalines*, 66 J. ORG. CHEM. 4050 (2001) (hereinafter "Mansour").

Mansour describes, among other N,N-dialkyl-p-nitroanalines, N,N-dipropyl-p-nitroanaline. (Pg. 4051). Mansour indicates that the N,N-dipropyl-p-nitroanaline was dissolved in and later precipitated from, methanol. (Pg.4054).

11. Claims 1, 3, 16, 30 ,35, and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Kunio Akahane, *b-Adrenoreceptor Blocking Effects of a Selective B2-Agonist, Mabuterol, on the isolated, blood perfused Right Atrium of the Dog*, 97 BR. J. PHARMACOL. 709 (1989) (hereinafter "Akahane").

Akahane describes a solution of mabuterol in physiological saline. (Pg. 710). Mabuterol anticipates the genus as described in instant Claims 1 and 30 when R_1 is CF_3, R_5 is halogen, $R_{2,4,6, \text{ and } 7}$ are hydrogen, and R_3 is "hydroxyalkyl" as defined in the specification.

12. Claims 1, 18, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,026,704 (hereinafter "Honore").

Honore describes N-cyclohexyl-4-cyano-2-nitroaniline. (C.14, L.17-29).

13. Claims 1, 18, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 3,507,903 (hereinafter "Gottschlich").

Gottschlich describes 2,6-dicyano-4-nitroanaline. (C.1, L.24-32).

14. Claims 1-3 and 16-18 are rejected under 35 U.S.C. 102(e) as being anticipated by International Patent Application Publication WO02/072540 (hereinafter "Annis").

Annis describes ortho-substituted toluenes of the formulas VIb and VIc. (Pg. 14). These compounds contain additional substituents R5 which include halogens, C1-4 alkyl, alkoxy, haloalkyl, haloalkoxy groups, phenyl or phenoxy groups. (*Id.*). Specifically, Annis discloses 2-methyl-4-(trifluoromethyl)aniline (Pg. 21), and a series of compounds in Table 1A. (Pg. 24-26).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. Claims 1, 18, 21-23, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,721,356 (hereinafter "Ugarkar").

Ugarkar describes adenosine kinase inhibitors such as the compounds of Formula 3 (C.7, L.26-51). These compounds feature a disubstituted aniline moiety where meta- and para-substituents are each independently halogen or cyano. (*Id.*)

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. *Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference does not provide any motivation to select this specific combination of variables such as para cyano with meta halogen such as chloro or meta cyano, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious." *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (*Id.*). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR v. Teleflex*, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is… a person of ordinary creativity, not an automaton." *Id.* at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of variables such as para cyano with meta halogen such as chloro or meta cyano from within a prior art disclosure, to arrive at compositions "yielding no more than one would expect from such an arrangement."

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-3, 16-20, 30, 32, 35, and 44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 and 6 of copending Application No. 11/911,537. Although the conflicting claims are not identical, they are not patentably distinct from each other because the generic claims of the instant application are rendered obvious over the generic compounds and compositions disclosed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 1-3, 16-20, 29, 30, 32, 35, 43, and 44 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 20 of copending Application No. 10/598,508. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds and compositions of the instant claims fall within the scope of the generic compounds and compositions of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

While no Claims are allowable as currently presented, the examiner has found the species elected by applicants, 4-[(Cyclopropylmethyl)(propyl)amino]-2-(trifluoromethyl)benzonitrile, appears free of the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean Basquill whose telephone number is (571) 270-5862. The examiner can normally be reached on Monday through Thursday, between 8AM and 6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Brandon J Fetterolf/
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